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(54) **Sensor for measuring a pressure profile**

(57) Pressure sensing device for measuring pressure profiles comprising :

- a flexible tubing,
- actuating means for moving a conductive solution within said flexible tubing,
- impedance measuring means for measuring the impedance of said solution,
- processing means for transforming an impedance profile into a pressure profile,

characterized by the fact that it furthermore comprises :

- conductive solution oscillating means.

EP 1 371 325 A1

Description

[0001] The present invention relates to a pressure sensing device and to a method for using said device. More precisely the invention concerns a device for measuring pressure profiles in mammals.

[0002] The Pressure Profile Sensor Method, defined as PPS-Method hereafter is disclosed in German patent DE 197 24 001 C1. It is based on the deformation applied by external pressure to a catheter which contains a saline solution. As the saline solution is electrically conducting, the impedance of the saline solution changes when the shape is changed through the applied pressure along the axis of the tubing (co-ordinates x) and over time (co-ordinates t). The most sensitive part of the saline solution column - to change the shape - is the front of the saline solution. That means the pressure profile (x) can be measured over time (therefore the word pressure profile sensor), p over x and t, p(x,t).

[0003] The inert mass of the saline solution column - being by total volume incompressible as all standard fluids - allows expansion only at the front of the saline solution column. At this end only a little inert mass needs to be moved by the force generated by the external pressure. The column portions being far away from the front need to move all the other column portions towards that front which results into continuously higher inert masses to be moved. The external pressure is not capable to do that after a certain very limited extend. To avoid a gas spring effect, the front of the saline solution can move forward in the saline solution lumen (with thin wall) connected to a venting lumen, that means at the tip of the PPS-catheter these two lumens are connected to each other. All that measures result into the situation that the front of the saline solution column has to be the place of measurement. The external pressure is causing there the geometrical changes of the shape of the saline solution resulting into a change of the impedance of the full saline solution column which can be measured by the PPS-machine and translated through an algorithm described in patent DE 197 24 001 C1 and in publication "Pressure Profile Sensing system" in Sensors and Actuators A93 (2001), 52-56, Elsevier Science B.V.

[0004] To find the pressure signal with the pressure sensitive front of the saline solution, the machine to control the placement of the saline solution column and to measure the impedance is equipped with hardware as well as software to correlate the pressure curves p(t) with the various locations x, a so-called pressure signal finding mode, abbr. PSFM.

[0005] If the tubing is a catheter inserted into an organism through e.g. a vessel then the user cannot see where the front of the saline solution column is located. This situation makes it very difficult and often impossible to correlate the pressure signals with the location x of the axis of the catheter.

[0006] The fast variations of pressure in the circulatory system are caused by the heart beating usually a little bit faster than one beat per second. The pressure profile over t can typically be displayed correctly if the measurement has a natural frequency response in the range of 20 Hz. That is usually also the response frequency of conventional pressure monitoring systems where the pressure signal enters into the tip opening of a catheter travelling through the inner lumen of the catheter into the saline solution filled tubing of the pressure monitoring set till the electrical chip-based transducer outside the body. And that has been proven as sufficient for already several decades. Only to mention the just described system of pressure recording can only measure the time profile of the pressure at the tip of the catheter. Only the pressure at one single place, not the pressure at the various locations along the length of the catheter or even only a small portion of it.

[0007] As already mention, when the PPS machine (with pump) is pushing the saline solution column into the catheter, the position of the front cannot be located when the catheter is "in-situ". The filling situation could be a measure if all the tubing (mainly from the transfer set with much higher filling volume) was exactly known with respect to its inner diameter. But this approach is unrealistic since the normal tolerances for such tubing of the transfer set are relatively high.

[0008] One of the major objectives of the present invention aims at measuring p(t) at different locations in an organism, i.e. where the front of the saline solution cannot be seen.

[0009] For that purpose the invention makes use of the advantage that in the organism the pressure curves p(t) can be correlated with the potential different locations of the catheter tips during insertion of the catheter, see e.g. "Essentials in Pressure Monitoring" by J. Cywinski, ISBN902472385X, pages 92 and 93, figures 18 and 19 (see drawings).

[0010] The invention therefore relates to a pressure sensing device as defined in claim 1. It also relates to a method of use of this device according to claim ... The basic concept of the invention is characterized by the fact the conductive solution column oscillates, preferably at about 20 Hz around search points x_0, resp. x_1 etc. to measure the pressure at that points. The oscillation can be generated by a special configuration of the motor and the pump head as well as the collection of the data $p(x_0)$, resp. $p(x_1)$ at running times t and then the display of p(t) at location x_0, resp. x_1 in real-time based on a special configuration of the algorithm of the program of the PPS method. It is important to keep the oscillating distance short (few mm) as otherwise the fast oscillation will cut or destroy the fluid column.

[0011] This procedure shall be applied step by step at proceeding locations x_0, x_1, x_2, (moving the front of the saline solution column towards the distal tip of the catheter). The pressure curves p(t) can then be displayed step by step (not simultaneously) at the locations x_0, x_1, x_2. As the physician knows the typical pressure curves from the conventional kind of pressure monitoring, and

there also with a resolution of 20 Hz, he can judge the location of the front of the saline solution column from the shape of the displayed pressure curve. This works independent from the potential calculations about the filling status of the PPS-transfer-set and the PPS-catheter and is more reliable than that. And exactly this correlation of the displayed p(t)-curves to the location of the front of the saline solution column is PSFM, the pressure signal finding mode.

[0012] When the catheter is filled according to the intended position, this position will be defined as "zero" and from there slow oscillations can scan the catheter in a wide range (several cm) in case the oscillation frequency is slow enough (e.g. 1/10 Hz) not to disturb the saline solution homogeneity due to the oscillations.

[0013] The recording of the impedance signal of the oscillating saline solution column according to the PPS method will be realised in real time that an analogue differentiator circuit is deriving from the leakage current the pressure value at the oscillating place x immediately, displaying these values on the ordinates continuing on the horizontal axis and therefore writing the curve p(t) at place x. This special measurement mode then allows the user to compare such p(t) curves with physiological wave forms to correlate to the measurement location x in terms of anatomy.

[0014] The pump head of the peristaltic pump can move a very small volume of 1-2 mm^3 by using a pump segment tubing of typically 1-1.5 mm inner diameter - much smaller than typically used for such pump segments for feeding infusion solutions for infusion therapy - to allow fast oscillations of the saline solution column up to 25 Hz.

[0015] This further comment is not related to PSFM, only to explain the kind of measurement following after PSFM:

[0016] To display the pressure curves p(t) at different locations "simultaneously" the oscillation shall have a small defined phase shift to the EKG and therefore to the pressure waves coming from the heart. The data will be collected till a full cycle of phase shifts will add up to a full period and then re-addressing the data $p(x_i)$ at ongoing times tj to p(t, frequency resolution 20 Hz) at different locations x_i. But as described, that is not fully realtime, the collection of data and re-addressing over e.g. 20 pressure cycles is necessary (for the frequency resolution of 20 Hz), that means around 20 seconds of measurement time.

[0017] For the (nearly) real time display of p(t) we cannot use this method in the paragraph above, the fast oscillating method must be used.. In patent DE 197 24 001 C1 a syringe pump is described driven by an excenter and a push-pull mechanic. Our own experiments which such kind of a construction show that even with best versions of syringes only a maximum oscillation frequency of 10 Hz can be achieved.

[0018] In addition the filling situation of the syringe and the connection tubing without air bubbles is very dif-

ficult to achieve. The normal user knows the procedure to fill standard pressure monitoring sets only from straight-through configurations, and even that is difficult. He would like to find such a situation again in the PPS method

[0019] It is therefore a preferred embodiment of this invention, based on the principles of the patent DE 197 24 001 C1 to use a peristaltic pump instead of a syringe pump plus replacing the linear motor - used normally to drive peristaltic pumps to get reliable feeding - by a stepper motor which can be triggered fast and discrete to fill the PPS-transfer-set plus PPS-catheter and to create fast as well as slow oscillations.

Claims

1. Pressure sensing device for measuring pressure profiles comprising :

   - a flexible tubing,
   - actuating means for moving a conductive solution within said flexible tubing,
   - impedance measuring means for measuring the impedance of said solution,
   - processing means for transforming an impedance profile into a pressure profile,

   characterized by the fact that it furthermore comprises :

   - conductive solution oscillating means.

2. Pressure sensing device according to claim 1 wherein said actuating means comprises a stepper motor.

3. Pressure sensing device according to claim 2 wherein said actuating means furthermore comprises a peristaltic pump.

4. Pressure sensing device according to claim 3 wherein the peristaltic pump segment is directly connected to said flexible tubing in such a way that pressure can be measured.

5. Pressure sensing device according to any of the previous claims comprising display means to display the geometry of said flexible tubing.

6. Pressure sensing device according to any of the previous claims comprising filling status means for indicating the approximate position of the front of the conductive solution.

7. Use of the device as defined in any of the previous claims **characterized by** the following steps :

a) oscillating the conductive solution within the flexible tubing around a first position defined by the front of the conductive solution,
b) recording the impedance signal of the oscillating solution,
c) transforming the impedance signal into a pressure signal,
d) comparing the resulting pressure profile with known pressure profiles,
e) determining the position of the front of the conductive solution and therefore the place where the pressure is measured.

8. Use of the device according to the previous claim furthermore comprising the following steps :

f) changing the position of the front of the conductive solution,
g) repeating previous steps a) to e) with the new position.

9. Use of the device according to claim 7 or 8 wherein the oscillating frequency is about 20 Hz.

10. Use of the device according to anyone of claims 7 to 9 wherein the amplitude of the oscillating ranges between 1 and 2 mm.

European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

EP 02 40 5490

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
D,A	DE 197 24 001 C (KNOLL) 1 October 1998 (1998-10-01) * the whole document *	1,7	A61B5/0215 G01L9/18 A61B5/06
A	WO 84 00290 A (BOMED MEDICAL MANUFACTURING LTD.) 2 February 1984 (1984-02-02) * page 11, line 32 - page 12, line 18 * * abstract; figures 1-4 *	1,7,9	
A	EP 0 990 883 A (XEROX CORP.) 5 April 2000 (2000-04-05) * abstract; figures 1-11 *	1,7	

TECHNICAL FIELDS SEARCHED (Int.Cl.7)

A61B
G01L

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	2 December 2002	Hunt, B

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ANNEX TO THE EUROPEAN SEARCH REPORT
ON EUROPEAN PATENT APPLICATION NO.

EP 02 40 5490

This annex lists the patent family members relating to the patent documents cited in the above-mentioned European search report.
The members are as contained in the European Patent Office EDP file on
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02-12-2002

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
DE 19724001	C	01-10-1998	DE	19724001 C1	01-10-1998
			WO	9856292 A1	17-12-1998
			EP	0986325 A1	22-03-2000
			JP	2002503121 T	29-01-2002
			US	6450972 B1	17-09-2002
WO 8400290	A	02-02-1984	WO	8400290 A1	02-02-1984
			AU	8822982 A	08-02-1984
			EP	0113345 A1	18-07-1984
			JP	59501296 T	26-07-1984
EP 990883	A	05-04-2000	US	6044717 A	04-04-2000
			EP	0990883 A2	05-04-2000
			JP	2000105156 A	11-04-2000

EPO FORM P0459

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82

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